PROJECT TITLE: Trabalhamos Juntos (We Work Together): Improving HIV care delivery by capacitating health care providers.

Clinical Trials Registration: NCT05938621

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Principal Investigators	Dr. Carolyn M. Audet, PhD, Institute for Global Health Vanderbilt University Medical Center, USA
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Location	Zambézia Province - Mozambique
Expected Start Date	30 July 2023
Expected End Date	30 March 2025
Type of Study	Randomized Controlled Pilot Trial
Main objective	Pilot two interventions to improve mental health and well-being among health care workers working with people living with HIV in Zambézia Province, Mozambique.
Key words	Health Care Worker Mental Health HIV care

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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
ART	Antiretroviral Therapy
C-Saúde	Centro pela Saúde Global
CCR	Child-at-risk Clinic
CFPS - HCB	Center of Training and Research in Beira Central Hospital ("*Centro de Formação e Pesquisa em Saúde – Hosptial Central de Beira*")
CI	Confidence interval
CPM	Cumulative probability model
DPS-Z	Provincial Directorate of Health of Zambézia ("*Direção Provincial de Saúde-Zambézia*")
EPTS	Electronic patient tracking system
FGH	Friends in Global Health
GoM	Government of Mozambique
HCW	Health care worker(s)
HIV	Human Immuno-deficiency Virus
MBWR	Mindfulness-based wellness and resilience
MOH	Ministry of Health
MPR	Medication possession ratio
NGO	Non-governmental organization
NID	Patient identification number
NIMH	National Institute of Mental Health
NIOZ	Operational Investigation Committee of Zambézia ("*Núcleo de Investigação Operacional de Zambézia*")
PEPFAR	United States President's Emergency Plan for AIDS Relief
PI	Principal Investigator
PLHIV	Person/People Living with HIV
PSS	Psychosocial Support
RCT	Randomized controlled trial
SOC	Standard of care
SSA	sub-Saharan African
VL	Viral load
VUMC	Vanderbilt University Medical Center
WHO	World Health Organization

1. Principal Investigator

The principal investigator (PI) for this evaluation will be Carolyn Marie Audet at Vanderbilt University Medical Center (VUMC). The PI will be responsible for all aspects of evaluation coordination, including design, implementation, and analysis.

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2. Funding

This project will be funded by a National Institute for Mental Health (NIMH) R34 award (PI. Audet).

3. Collaborators

Various project staff from the Ministry of Health (MOH) and Centro pela Saúde Global (C-Saúde)/Vanderbilt University Medical Center (VUMC) [1] will be involved in this activity (see **Table 1**). From the MOH, this includes an assigned member of the NIOZ (Dr. Arifo Aboobacar), and a member of CFPS-HCB (Vasco Cumbe, PhD, MSc, MD, Psychiatrist). From C-Saúde, this includes Caroline De Schacht, MD, MSc, PhD, Paula Paulo and Eusébio Maposse. From VUMC this includes Carolyn Audet, PhD, and Erin Graves, BSN, MPH.

Table 1. Collaborators in the study.

Name	Organization	Role	Role in the Evaluation
Arifo Aboobacar	DPS-Z, NIOZ	Collaborator	NIOZ Focal Point; Technical oversight
Caroline De Schacht	C-Saúde, Director of Evaluations	Co-investigator	Technical oversight; support to Study Manager

[1] All program activities transitioned from Vanderbilt University Medical Center (VUMC)'s affiliate organization, Friends in Global Health (FGH), to the Mozambican non-profit association Centro Pela Saúde Global (C-Saúde), with FGH staff contracts transferring to C-Saúde as of October 2024. The implementation of all Mozambique-based study activities will be carried out by the same individuals who have been part of the study team since project conception.

Vasco Cumbe	CFPS HCB	Co-investigator, Mental Health Consultant	Support in the development and implementation of provider-focused interventions
Paula Paulo	C-Saúde, Provincial Evaluations Coordinator	Collaborator	Coordination and supervision of study, technical oversight
Eusébio Maposse	C-Saúde, Developer	Collaborator	Coordination; support for clinical data extraction
Erin Graves	VUMC, Lead Program Manager	Collaborator	Technical and administrative oversight
Carolyn Audet	VUMC, Associate Professor	Principal Investigator	Technical oversight and mentoring
Bryan Shepherd	VUMC, Biostatistician	Collaborator	Statistical analysis support

4. Introduction and Justification

The setting. Friends in Global Health (FGH), a Vanderbilt University Medical Center (VUMC)-affiliated non-governmental organization (NGO), partners with the Ministry of Health (MOH) to provide clinical support to currently 149 health care facilities in the province. As of October 2024, all activities transitioned to the newly established national organization C-Saúde (please see footnote above). Evidence-based interventions address barriers to treatment retention by emphasizing a more patient-centered approach via community antiretroviral therapy (ART) distribution points,[1,2] adherence clubs,[2-6] home-based and spaced refill visits,[7,8] and employing community health workers (CHW) for ART provision and education.[9-12] Despite these efforts, only 87% of people who test HIV-positive remain in care at 12 months (FGH program data, March 2023).

Who is struggling with ART adherence? People with low levels of education, living in poverty, and under 35 years old have lower rates of retention and adherence to treatment in Mozambique,[4,13] similar to trends in other sub-Saharan African (SSA) countries.[14-16]

Interventions have attempted to address social, financial, and educational barriers. A review of qualitative factors impacting ART adherence in SSA yields examples of social (HIV stigma, poverty stigma), individual (trust, health beliefs), and structural (health care organizations, delivery, costs) factors serving as barriers to HIV treatment adherence.[3,4,17-20] Stigma can influence adherence, particularly if someone has not disclosed their HIV status to their family.[21-23] A combination of interventions in Mozambique, including the employment of peer educators, availability of psychological counseling services, and local media campaigns have led to

decreased stigma and increased HIV knowledge both among people living with HIV (PLHIV) and community members, but enacted stigma within intimate partner relationships remains a concern, particularly among women.[22,24] Men have historically been less willing to attend clinical services at health facilities, seen as women-dominated spaces, given the association of health facilities with childbirth and related perinatal services. Male engagement in antenatal care services, including HIV counseling and testing, has led to dramatic increases in HIV testing and treatment initiation among men,[23] but retention remains an issue. Male-friendly clinics have been piloted (based on a Kenyan model)[25] with a focus on offering male health providers, extended hours services, and supportive health care that goes beyond HIV to reduce potential stigma and provide socially acceptable treatment services for men.[25] Recently these clinical were expanded to anyone who needed services beyond the daytime, allowing anyone working to attend clinical appointments. Additionally, community adherence support groups, created to reduce the frequency of medication pick-up visits (which are often financially and logistically challenging for patients)[26,27] have been successfully employed among some patients in Mozambique to overcome these barriers.[6] Despite these efforts, patient retention remains sub-optimal. What can we do? We can start by listening to PLHIV who are receiving care in and to health care workers (HCW) who are providing services to PLHIV in these communities.

Patients report experiencing poor quality health care, including rude behavior by providers. This poor quality care includes perceived punishment (e.g., making patients wait excessively long before being attended to) for using traditional medicine, verbally abusing patients for not understanding instructions/directions, refusing to treat patients who lose their HIV registration card, and ignoring patient concerns about treatment side effects or opportunistic infections.[26,28-35] Our team has documented that poor treatment experienced by patients at the health facility (HF) appears to be fueled by two factors: (1) multiple stigmas (including HIV stigma) directed at the patient population, and (2) provider burnout and dissatisfaction with their jobs.[36-43]

Health care worker burnout is a global crisis. Burnout among health care providers in SSA is common.[36,38,40,41,44,45] Health care provider burnout can be defined as "a long-term stress reaction marked by emotional exhaustion, depersonalization, and a lack of sense of personal accomplishment."[46] Clinician burnout across SSA is an urgent problem, with more than 62% of providers in Malawi, between 21% - 72% in South Africa, and 23- 51% in Zambia experiencing burnout.[38,42,43,45] Delivery of quality health care services in extremely resource-limited settings can be grueling for front line health care providers. Frequent stock outs of essential medications,[47] a lack of qualified clinicians to assist in treating the long queue of patients,[48] providers assigned to communities with different languages/cultures than their own (there are 43 different languages spoken in Mozambique),[26] and insufficient infrastructure[49] can be overwhelming for even the best-trained and motivated providers. Health care workers facing unfamiliar and challenging work environments are also at risk for moral injury in their workplace, which "can occur when someone engages in, fails to prevent, or witnesses acts that conflict with their values or beliefs."[50] Experiences that are morally injurious may contribute to negative consequences in one's own behavior, attitude, and/or well-being. In SSA, there is little formal psychosocial support for health care providers based at health facilities.[51] Given that many providers live alone (with spouses and children based in large cities), there is often a lack of built-in family support in the locations where providers work.[52-54] This isolation and lack of support can compound provider exhaustion, which may manifest as excessive frustration with patients who miss appointments, do not pick up medications on time, lose their identification cards, or challenge provider treatment recommendations.[27,30,31,55-57] While the U.S. President's Emergency Plan for AIDS Relief

(PEPFAR), the Global Fund, and Mozambican government funds are being employed to improve quality of care, and while these health systems experience slow, incremental improvements, we have the obligation and opportunity to study interventions that address provider well-being, including job satisfaction, burnout, and emotional stability.

HIV-related stigma among health care workers results in poor patient outcomes. There have been recent calls to address the pressing issue of HIV stigma in the health system.[35] HIV stigma is pervasive in SSA at multiple levels, including systemic, interpersonal, and internal. Perceived community- or health facility-level stigma influences internalized stigma, which results in poorer treatment outcomes, social isolation, and poorer quality of life among PLHIV.[58] HIV stigma is largely driven by misconceptions about HIV transmission (i.e., fear of contracting HIV while treating an HIV-positive patient), lack of awareness about the negative impact stigma has on PLHIV, perceived moral transgressions made by those living with HIV (e.g., the person brought their diagnosis upon themselves), and pre-existing negative attitudes towards marginalized groups more likely to contract HIV.[35,58] If patients perceive their clinicians to hold negative attitudes towards them due to their HIV status or their association with another marginalized group (e.g., those who are poor, seek care from traditional medicine, do not understand the germ theory of disease), they are less likely to adhere to medication and remain in care.[35]

Summary of background and potential of *Trabalhamos Juntos (We Work Together)*. We propose to pilot a novel intervention that provides health care workers the skills, confidence, and support structures necessary to improve clinical care delivery, leading to increased retention and adherence to ART in Mozambique. Health care providers need the correct tools to reduce prejudice and sustain empathetic and sympathetic health care delivery in under-capacitated health facilities. The combination of an intervention to address provider burnout and an intervention to address stigmatizing attitudes towards patients will ensure that PLHIV receive the best possible care.

5. Objectives

The overall goal of this project is to assess the impact of two health care worker interventions designed to improve the mental health and well-being of health care workers in Zambézia Province, Mozambique.

Our specific objectives are as follows:

Objective 1: Evaluate the impact of resilience training only, anti-stigma training only, and resilience and anti-stigma training (vs. standard of care) on hypothesized mechanisms of behavior change among health care workers through a pilot cluster randomized controlled trial (RCT).

Hypothesis 1: We hypothesize that health care workers who participate in this training will report a significant reduction in stigmatizing attitudes towards their patients,[59] increased resilience,[60] decreased emotional exhaustion, and decreased depersonalization[61] of their patients.

Objective 2: Investigate the impact of health care worker training to reduce stigma and increase wellness and resilience on patient adherence to HIV treatment and satisfaction with health services.

Hypothesis 2: We hypothesize that patients receiving care at the site randomized to both resilience and anti-stigma training will have increased adherence to medication (as determined by proportion of time on medication and self-report) at 6 months, higher rates of viral suppression at 6 months, and increased satisfaction at 6 months.

Objective 3: Assess experience of moral trauma depression, anxiety and suicidal ideation among health care workers, and explore the perspectives of services/ interventions that could support those at risk of or experiencing moral trauma.

Hypothesis: We hypothesize that understanding the experiences and suggestions on mitigating will support development or improvement of interventions that increase wellbeing of health care workers. We will also capture baseline moral injury among health care workers as well as depression, anxiety, and suicidal ideation among health care workers at 10-11 months post intervention.

6. Design and Study Questions

We propose to conduct a pilot cluster randomized controlled trial to evaluate the effects of our interventions. Four health care facilities in Zambézia Province will be selected and then randomized to the control (standard-of-care [SOC]) or the intervention arms (anti-stigma training ONLY, resilience training ONLY, or anti-stigma + resilience trainings) (i.e., there will be one control arm and three intervention arms).

There are six specific study questions:

Question 1: Does our resilience/wellness intervention improve health care worker mental health outcomes?

Question 2: Does our anti-stigma intervention reduce stigma towards patients?

Question 3: Do health care workers who receive these interventions have suggestions about how they could be improved?

Question 4: Do our interventional trainings have any impact on patient adherence to HIV treatment?

Question 5: Do HCW in this area experience or have risk for moral injury/ moral trauma, and what services/interventions do HCW think could be supportive if experiencing this?

Question 6: Do HCW in this area experience depression, anxiety or suicidal ideation?

7. Study Population

a. Population:

1. PLHIV: Adult individuals enrolled in HIV care and treatment at one of the study sites.

2. Health Care Workers: Physicians, nurses, medical technicians, health counselors, community health care workers, and other clinical and non-clinical (e.g., receptionists, data entry clerk) staff who are providing health services to adult PLHIV.

b. Inclusion/Exclusion Criteria:

1. PLHIV (for medical file review)

Inclusion:

- Adult individuals, 18 years of age or older
- Active in care (i.e., not in default)
- Receiving HIV care and treatment at one of the four study sites.

2. PLHIV (for survey participation)

Inclusion:

- Adult individuals, 18 years of age or older
- Active in care (i.e., not in default)
- Receiving HIV care and treatment at one of the four study sites.
- Sought care at health facility on the day of survey data collection

Exclusion (for survey participation only):

- Any clinical or mental condition (for example, but not limited to: patients with delusions, hallucinations, impaired cognitive function, mental retardation, medical condition with physical deterioration, or under the influence of drugs or alcohol at the time of study recruitment), that as per the investigator's opinion/assessment, would preclude provision of informed consent or make study participation unsafe or unethical;
- Being at the health facility for reasons other than their own medical appointment and/or picking up their own medication;
- Those who do not have routine care at the selected health facility (e.g., individuals who receive HIV care and treatment at a different facility than their own due to stigma or other reasons).

3. Health Care Workers

Inclusion:

- Adult individuals, 18 years of age or older;
- working as physicians, nurses, medical technicians, health counselors, community health care workers, or other clinical and non-clinical staff (e.g.,

receptionists, data entry clerk) who provide health services to adults living with HIV at one of the four study sites;
- willing to be followed as a study participant during the 6-month study period, and does not intend to transfer to another HF during the study period (per investigator's assessment at time of recruitment), as self-reported.
- Be able to read and write in Portuguese, as self-reported.

Exclusion:

- Those who are not permanent members of the health facility staff (i.e., floating providers that work at multiple sites in a given week);
- Any clinical or mental condition, including influence of drugs or alcohol at the time of study recruitment, that as per the investigator's opinion/assessment, would preclude provision of informed consent or make study participation unsafe or unethical;
- Individuals working in the health facility but from the following cadres: drivers, security personnel, and workers who do not have any patient-facing roles.

c. Calculations of Sample Size:

Objective 1: Each of the four selected sites have no more than 25 health care workers providing HIV care, so we anticipate a maximum total of 100 health care workers equally divided between each intervention arm and the control arm. With n=25 in all arms, assuming an intraclass correlation coefficient (ICC)=0.10, and two-sided type I error rate of 0.05, then we anticipate that we will have approximately 80% power to detect a difference of 1.07 standard deviations of the outcome (e.g., change in resilience score between baseline and after intervention), or the change in stigma score between baseline and after intervention) between the intervention vs. control for each of the two interventions. If ICC=0.05 (or 0.15), then we will have approximately 80% power to detect a difference of 0.85 (or 1.26) standard deviations.

For our qualitative interviews, we will continue to collect data until we have reached data saturation. Based on similar interviews conducted in 2022 (unpublished, IRB# 99/CIBS-Z/22), we believe we will reach saturation with no more than 40 interviews.

Objective 2: Each of the four health facility sites serve at least 4,000 patients enrolled on ART who will be scheduled for clinic visit(s) during the study period. With a minimum of n=4,000 in each facility, assuming an ICC=0.05, and two-sided type I error rate of 0.05, then we anticipate that we will have approximately 80% power to detect a difference of 0.64 standard deviations of the outcome (e.g., proportion of time on medication) between the intervention vs. control. If ICC=0.025 (or 0.10), then we will have approximately 80% power to detect a difference of 0.45 (or 0.91) standard deviations.

The survey will be done in a sub-population of the cohort of HIV-positive patients at all four sites. Due to the exploratory nature, sample sizes for the patient surveys were not calculated based on existing assumptions. We estimate that 80 surveys per HF (n=320) will provide us with the requisite baseline preliminary data on how they experience health care. For outcome

measures available on only these surveyed participants, we anticipate approximately 80% power to detect differences of 0.55, 0.71, and 0.96 standard deviations of the outcome assuming ICC of 0.025, 0.05, and 0.10, respectively.

Objective 3: For the qualitative interviews for this objective, we will collect data until we have reached data saturation. Based on similar interviews conducted in 2022 (unpublished, IRB# 99/CIBS-Z/22), we believe we will reach saturation with between 20-40 interviews, with no more than 40 interviews. For the surveys related to anxiety, depression and suicidal ideation the goal is to reach all of those involved in our baseline assessments, 100 health care workers.

d. Sampling

1. PLHIV participants: All adults receiving HIV care and treatment at the study sites will be included (including from adult care services sector, antenatal care [ANC] sector, Child-at-Risk Clinic [CCR], and those receiving joint TB/HIV care services). We aim to have a similar proportion of males and females, and from the different sectors.
2. Health care worker participants: All health care workers who are eligible will be invited to participate in the study. We will focus on identifying participants from different sectors (HIV, TB, maternal health) and levels (nurses, medical technicians, physicians, etc.) and aim to have a similar proportion of males and females.

e. Participant recruitment, retention, and withdrawal:

1. For Objectives 1 - 3:
   Recruitment:
   Health care workers (intervention, survey, in-depth interviews): The study team will perform information sessions at the health facility to explain the study. We will request to the head clinician that all health care workers attend to ensure everyone has a chance to learn about the project. If the health care worker is interested in participating, their informed consent will be obtained by a study assistant at the health facility or in a location of their preference. For the intervention and survey, we will recruit at convenience, and enroll all interested and eligible participants. For the in-depth interviews (Objective 1) that will be conducted within one month of the completion of sessions, we will attempt to enroll an equal number of HCW by facility and sector, so we will use purposive sampling to select individuals we believe can add varying views to the study findings. Health care workers can withdraw at any time without impact on their clinical position. For the in-depth interviews (Objective 3) related specifically to HCWs' perspectives and experiences of moral injury/ moral trauma, we will contact HCW who had consented to enrollment in the study at intervention sites. For the depression/anxiety surveys that will occur approximately 10-11 months after the intervention, we will also contact HCW who consented to be enrolled at both intervention and control sites and will re-consent HCW. We will inform them of the opportunity to participate in one additional interview or survey and explain the objective of this interview. If the HCW is interested in participating, their informed consent will be obtained by a study assistant at the health facility or in a location of their preference. For this interview with a sub-set of the intervention participant population, we will attempt to enroll an equal number/ proportion of HCW by sex, by health facility, and by category/clinical role of HCW, using purposive sampling to select individuals

we believe can add varying views to the study findings. These HCW can withdraw at any time without impact on their professional position.

People living with HIV (survey): The study team will recruit participants to complete the baseline and endline surveys at the time the individuals are leaving an appointment for HIV care at one of four eligible health care facilities. Recruitment will be done using convenience sampling when the individual exits the health facility after receiving care. If the individual is interested in participating in the study, a study assistant will bring them into a private room to discuss their eligibility and study procedures (complete surveys at study baseline or endline, i.e., 6 months after the study begins, and to the use of a subset of data from their medical records regarding ART medication pick-up history within the previous 6 months). If eligible and they agree to participate, their informed consent will be obtained by the study assistant at the health facility. Participants and withdraw at any time without impact on the clinical care they are receiving.

People living with HIV who are followed as part of routine care (estimated n=16,000): The study team will not formally recruit and consent these individuals to participate in the study, as only a chart review will be performed. For the inclusion of these individuals' data, we will seek a waiver of informed consent, to be developed and included in the submission to the ethics committees/Institutional Review Board (IRB), to access their retention data and viral load results over the course of the study.

Retention in the Study:
Health care workers who agree to participate in the training program will be encouraged to complete all sessions. During each session, a snack will be offered, as sessions will occur in the afternoon. Additionally, a certificate of completion for those who participate in each session will be provided, and there will be the option for those who complete all the intervention sessions to be first in line for the any subsequent training of trainers sessions to lead future groups at each facility. Related to retention to study activities, specifically the survey and/or in-depth interview activities, our study personnel will ask for permission to reach out to participants via phone (call and/or text) if they miss their study-related data collection appointment. This number will be destroyed when the study finishes.

Withdrawal from the Study
Health care workers and PLHIV can withdraw from the study at any time without consequence. If a participant wishes to withdraw, we would ask for them to communicate with our study manager.

8. Methods

a. Study Procedures

Objective 1: Resilience Intervention and Anti-Stigma Intervention on health care worker behavior

We will assess the success of each element of the multi-component intervention with a pilot cluster randomized controlled trial (RCT) at four health facilities (see **Figure 1**). Although a fully powered cluster RCT with multiple health facilities randomized to each arm is outside the scope of this study, the delivery of a health care worker team wellness intervention requires a health facility-based approach.

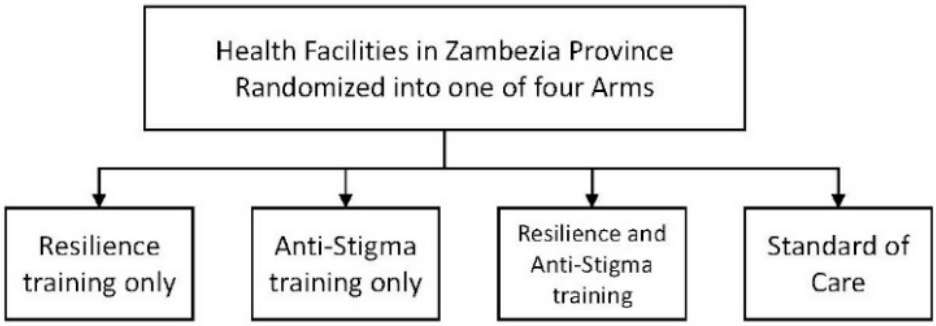

Figure 1: Study Design

Intervention designs

All intervention sessions (wellness/resilience-related and burnout-related) will offer a didactic (educational) component and a practical (e.g., interactive) component to allow for participants to learn about the session topic(s) and to practice the skills and activities discussed/proposed in a dedicated time/space with support from session facilitators.

Wellness and Resilience Intervention

Health care workers working at sites randomized to resilience training or the combination anti-stigma and resilience training will receive a group-based Mindfulness-based Wellness and Resilience (MBWR) intervention. The training course will occur every other week and consist of 4 sessions of 60-120 minutes each. The day and time of the intervention session will be determined by health facility staff to facilitate attendance. We will focus on common challenges encountered in the health facility, as well as coping strategies, and future goals to improve provider well-being.

The team selected a group-based, mindfulness-based wellness and resilience (MBWR) intervention. MBWR is designed to be a brief, cost-effective, evidence-based, and replicable intervention to enhance resilience and self-compassion among teams providing primary health care services.[62] The training is based on an established Mindful Practice curriculum[63] and Mindfulness-Based Stress Reduction curriculum.[64] This intervention was selected because it focuses on developing resilience and self-care at the team level (which is how HIV care and treatment is delivered) and because the training can be conducted by a trained Bachelor-level psychologist. The original training course consists of weekly sessions of 60-120 minutes each over 6-10 weeks. Our team has adapted the curriculum to include common challenges encountered in these health facilities, facility-level strategies that can empower health care workers to improve conditions, individual coping strategies, and future goals to improve HCW well-being (see **Table 2**).

Table 2: Adapted Wellness and Resilience Training Topics

Focus of Resilience Training Sessions	Intended Learning outcomes
1) Burnout and its consequences and ways to respond/ when to seek care	• Factors that may lead to the feeling/ experience of burnout; • Understand the signs and symptoms of burn-out and the consequences of not-identified burn-out among health care workers; • Getting skills to help colleagues in identifying symptoms; • Know how to recognize burnout and where to refer to if experiencing symptoms; • *Interactive component:* share ways that burnout impacts either yourself or colleagues who you work with.
2) Self-care and ways to cope with work-related stressors & Teamwork and social support	• Getting coping strategies skills to overcome some work-related stressors; • When and how to seek care from others/ a professional; • *Interactive component*: practice examples of self-care (e.g., meditation, breathing exercises, etc.). • Understand the importance of teamwork/ social support in the prevention of work-related stress and in the provision of better patient care; • *Interactive component*: brainstorming ideas for social support/group activities that could be supported by and/or at the workplace.
3) Communicating and managing interpersonal relationships with others (ex. colleagues, patients, etc.), conflict handling in the work setting	• How to better communicate with others in the workplace and resolve work setting conflicts; • Ways to advocate for self and communicate expectations among team members; • *Interactive component*: what options for improving communication and/or interacting with others might work at your facility; role play with other participants to practice navigating difficult conversations (e.g., in pairs, could share with larger group).
4) Finding better balance between life and work activities/responsibilities	• Describe responsibilities that one may juggle between life and work; • Discuss ways to build healthier balance in work and life activities/priorities; • Interactive component: pairs or small group discussions for personal experiences of 'juggling' responsibilities, brainstorming ways to have better balance.

<u>Anti-Stigma Intervention</u>

Health care workers working at sites randomized to the anti-stigma only or the combination anti-stigma and resilience arm will receive anti-stigma training sessions to address issues with multiple stigmas that may be impacting their ability to provide quality care for PLHIV in Mozambique. The training will occur once every other week, for at least 4 sessions of 60-120 minutes each. The day and time of the intervention session will be determined by health facility staff to facilitate attendance.

Study personnel will work with health care workers at study sites to combine and adapt the most applicable components from three evidence-based anti-stigma interventions.[59,65,66] These interventions were selected because: i) they were developed in low and middle income settings (and parts of one intervention have been tested in Mozambique through International Association of Providers of AIDS Care [IAPAC] modules), ii) their focus is on identifying HIV-related and other intersecting stigmas, the impact stigma has on patients, the impact stigmatized beliefs have on health care providers, and iii) they propose ways to create a stigma-free environment in the health setting (see **Table 3**).[59,65,66]

Table 3: Adapted Anti-Stigma Sessions

Title of exercise/session	Intended learning outcomes
1. Naming stigma through pictures/defining stigma; describing the different types of stigma; consequences of stigma	• Participants discuss what similar stigma takes place in different contexts and start to share stories of what they have personally witnessed. • Recognition of how personal attitudes and beliefs influence stigmatizing behavior. • Helps participants to recognize the causes of stigma and how the resulting effects are manifested. • *Interactive component*: brainstorming as a group the types of and expressions of stigma in the workplace.
2. Communication skills with patients to avoid stigmatizing them	• Discussing and giving examples of stigmatizing communication with PLHIV. • Discussing and giving examples of non-stigmatizing communication with PLHIV. • Correlate stigmatizing communications and its consequences on the care of PLHIV. • Correlate non-stigmatizing communications and its consequences on the care of PLHIV. • *Interactive component*: in pairs, example case scenarios and practice communication styles.
3. Communication skills to improve relationship with patients in situations where you (the provider) are uncomfortable	• Participants discuss difficult situations for communication. • Participants discuss examples of stigmatizing and non-stigmatizing communication in situations where patients are complaining; in situations where patients are rude or dismissive; in situations where provider feels uncomfortable when attending patients' part of key population; • *Interactive component*: discuss as a group about questions and/or potential examples when the provider did not feel informed or knowing how to respond; examples of difficult interactions and options for how to respond in those situations.
4. Humanization session to facilitate better understanding of the challenges faced by patients.	• Getting skills on how to explore on a regular basis the challenges faced by patients and how to strengthen the patient to overcome some of these challenges; • *Interactive component*: example case scenarios and ask group to offer possible factors that influenced the 'why' of that situation to practice empathetic thinking and compassion skills for patients' experiences.

Procedures for Health Care Workers

Survey Data Collection (Objectives 1 and 3)

All health care workers who agree to enroll in the study will be asked to complete study questionnaires i) at baseline, ii) within 1 month after last session (or 6 months after enrollment in the control site), and iii) approximately 10-11 months after enrollment. Sociodemographic data will be collected within the baseline survey. We will measure HCW attitudes (n=100) towards their patients (stigma),[59,67-69] as well as factors associated with well-being, including resilience,[60] burnout,[61] depersonalization,[61] moral injury,[70] depression[71] (endline only), anxiety[72] (endline only), and the Suicide Screening (endline only)[73] (see **Table 4**; see **Appendix 1** for each measure). Details on the co-primary outcomes are noted below.

Qualitative Interview Data Collection (Objective 1)

We will conduct in-depth interviews with a maximum of 40 HCW within 1 month of the intervention completion. Qualitative interviews will focus on assessing factors associated with reach (who felt included/excluded; did subsets of groups drop-out?), effectiveness (perception of intervention success including changes in feelings towards patients, strategies adopted to improve wellness and resilience, experiences interacting with patients), adoption (facility- or provider-level barriers to adoption), implementation (capacity, adaptations necessary), and maintenance (barriers to sustainability, champions for sustainability).

Table 4: Measures (HCW)
Measures collected via surveys with HCW at baseline, and 1 month after the last session (6 months after baseline in the control site):
(1) Resilience[60]
(2) HIV Stigma[67-69]
(4) Burnout[61]
(5) Depersonalization[61]
(6) Moral Injury Questionnaire*[70]
(7) Depression[71] #
(8) Anxiety[72#]
(9) Suicide Screening[73#]
[**Only to be done at baseline*
#*Only to be done at endline*]

Qualitative Interview on Moral Injury Data Collection (Objective 3)

We will conduct in-depth interviews, 20-40 (with a maximum of 40 HCW), from intervention sites. Qualitative interviews will focus on assessing HCWs' perspectives on the presence of moral injury/ moral trauma among HCW in this area, how the experience of moral injury/ moral trauma may impact HCWs' work and/or wellness, and what services or interventions may be supportive for those experiencing or at risk for experiencing moral injury/ moral trauma.

Procedures for Patients living with HIV

Procedures for PLHIV who have agreed to participate in the survey.

Survey administration with PLHIV participants enrolled in the study will be completed at two time points: one at baseline (i.e., study initiation) and one at endline (i.e., at 6-7 months after study initiation), including sociodemographic data and three questionnaire components related to: Medical Mistrust,[74] Patient Satisfaction,[75] and Perceived stigma from Health care Providers[76,77] (**Appendix 2**). The survey will be done at the health facility or at a location suggested by the participant as per the participant's preference, at a location where privacy can be guaranteed as much as possible with the support from a surveyor who is fluent in Echuabo (local language). Participants may be recruited for more than one survey time point, however, different PLHIV participants can be recruited at the two time points. Participants will be requested to allow the use

of a subset of data related to their ART medication pick-up history for the past 6 months will be collected from their medical records for use in analyzing the survey data (**Appendix 10**). These data will be extracted from the electronic patient tracking system OpenMRS™, which stores clinical information form the medical records of PLHIV registered at the health facility.

Procedures for PLHIV for whom we will collect routine clinical data.

We intend to collect demographic and clinical data from patients' medical records that include, but are not limited to: HF, NID, age, sex, level of education, marital status at enrollment in HIV care, date of enrollment in HIV care, date of ART initiation, ARV, Body mass index (BMI), CD4+ T-cell count, HIV-1 viral load (VL) (data and value), WHO clinical stage at the first visit and ART initiation, hemoglobin and full blood count on the date of enrollment in HIV care (or nearest), residence (urban or rural), and records of ART pick-ups (to assess retention) (**Appendix 9**). Data will be extracted from the electronic patient tracking system OpenMRS, that stores clinical information form the medical records of PLHIV registered at the health facility.

b. Measurement of Results

HCW Outcomes: We will assess the effect of our anti-stigma and resilience training programs on several proposed mechanisms of change among health care workers. These intermediate outcomes, described in **Table 4**, are strongly correlated with improved patient outcomes in large studies around the globe.[17,19,59,78-80]

Co-primary outcome - resilience: We will assess resilience among HCW using Early Warning Resilience Survey.[60] The measure captures data on two subscales (Decompression and Activation) through responses to 8 statements, including, "*I can enjoy my personal time without focusing on work matters,*" "*The work I do makes a real difference,*" and "*I rarely lose sleep over work issues.*"

Co-primary outcome – HIV stigma: We will use an assessment of general HIV stigma from the Visser et al. HIV stigma measure validated in South Africa.[69] The general HIV stigma measure includes items from two factors: (i) blame and judgement and (ii) interpersonal/social distancing.

Outcome – anxiety, depression, suicidal ideation: Depression using the PHQ-9 MZ tool[71] (endline only), anxiety using the GAD-7[72] (endline only), and suicidal ideation using the Suicide Screening tool (endline only)[73]

Patient Outcomes: Our primary measure of effectiveness will focus on patient medication adherence (as measured by proportion of time on medication, see p. 20 for definition), retention (to scheduled clinical appointments and ART pick-ups), and most recent viral load in past 6 months after enrollment (see **Appendix 9**). We will also assess patient outcomes via surveys with PLHIV participants to assess their perception of provider compassion and communication during their clinical visit, as well as how their experience compared with the care they anticipated receiving (based on previous experience and the experience of others in their family/community). The measures used in surveys with patients include Medical Mistrust,[74] Patient Satisfaction,[75] and Perceived Stigma from Health care Providers[76,77].

c. Anticipated end date of study:

This study is expected to be concluded in December 2025.

9. Locations of Study

VUMC/C-Saúde supports HIV care and treatment services in 149 clinical sites in the province. These sites range from small district-level hospitals to rural health posts. Our trial will involve four of these clinics (with a focus on urban facilities): 1) as a control site, 2) as a site implementing anti-stigma training, 3) as a site implementing resilience training, and 4) as a site implementing anti-stigma and resilience training.

Health facilities will be eligible for selection in the study if they serve at least 4,000 patients enrolled on ART who will be scheduled for clinic visit(s) during the study period. For study operational purposes, only HF in Quelimane City and Nicoadala districts will be considered for selection. **Table 5** below shows a list of health facilities meeting these criteria and from which study sites will be selected by study co-investigators in collaboration with DPS-Z/NIOZ study focal point. Site selection will also consider feasibility of study activities at the indicated HF.

Table 5: List of Health Facilities Eligible for Study Site Selection

	HF Sites Eligible for Study Selection			
	District	**Health facility**	**# of patients in Q1 (Oct – Dec 2022)**	**# of patients in Q2 (Jan – Mar 2023)**
1	Nicoadala	CS Nicoadala	13113	12580
2	Quelimane	CS 17 de Setembro	7761	7637
3	Quelimane	CS Coalane	7074	6981
4	Nicoadala	CS Licuare	5882	6030
5	Quelimane	CS 24 de Julho	5921	5917
6	Quelimane	CS Chabeco	4698	4727
7	Quelimane	CS Namuinho	4741	4422
8	Quelimane	CS 4 de Dezembro	4180	4149

10. Data Management and Analysis

Data Management and Security

Survey data: Data from the surveys, including sociodemographic data, will be entered into a secure, password-protected REDCap database by field staff trained in data entry using password-protected tablet devices. Data are kept in the VUMC-REDCap server. In the event that paper surveys are necessary to use (e.g., connectivity to REDCap database is temporarily unavailable), data will be initially captured on the paper survey and later entered into a REDCap database by field staff trained in data entry. In these cases, the original paper surveys will be locked in a file

cabinet in the C-Saude office in Quelimane for 5 years, after which time they will be destroyed once authorization by the PI (Dr. Audet) is received.

In-depth interview data: The in-depth interview data will be recorded; research staff will transcribe the data ideally within a month of the interview into a password protected Word document. After transcription and translation, the original recording will be deleted. Only the study team working on the analysis will have access to the interview data. The data files will be password-protected to ensure confidentiality.

Data from interviews will be transcribed (and if necessary translated from local language into Portuguese) at C-Saúde Quelimane office. Transcription data will be typed up into Word documents, and subsequently translated into English. We will randomly select 10% of the original interviews to be re-translated (back to Portuguese) to check for accuracy after translation. The English transcriptions will be imported into MAXQDA 2022® software or similar to be coded by Dr. Audet and a study assistant. The data will be password-protected to ensure confidentiality and will be stored in REDCAP to ensure security and backup of data.

The original audio recordings of the interviews, which will not include participant names or other identifiable information, will be locked in a file cabinet in the C-Saude office in Quelimane until they have been entered into the database and the data has been checked for errors. After this point they will be erased to ensure voices cannot be linked back to the transcripts. All paper copies of transcripts will be destroyed once they have been typed up, verified, and the electronic versions have been sent to VUMC. All electronic copies of transcripts will be kept in a password-protected folder on a secure server at VUMC for a period of 5 years, after which time they will be destroyed after authorization of the PI (Dr. Audet) to do so.

Routine clinical data: C-Saúde and other PEPFAR partner organizations within the province implement electronic patient tracking system (EPTS) databases using OpenMRS, to collect patient information on their HIV care, facilitating the maintenance of these records for the MOH's program. Data are extracted from patient clinical records into electronic patient tracking systems already established and functioning as part of routine monitoring by C-Saúde data entry specialists.
The OpenMRS databases are password protected and can only be accessed by C-Saúde monitoring and evaluation staff. The staff have specific training on data confidentiality; all C-Saúde staff sign confidentiality agreements prior to having any contact with patient clinical files. All data are reviewed by C-Saúde data supervisors at the district level and by data analysis officers based in the C-Saúde provincial office in Quelimane. Corrective measures are taken as necessary as a result of data quality audits and regular reviews of data. For this project, de-identified data will be extracted into a restricted dataset by C-Saúde employees from the existing OpenMRS databases and sent to a VUMC Biostatistician for analysis. All routine programmatic data are owned by the MOH. All routine programmatic data are part of the clinical record and as such will not be destroyed.

Data Analysis

Objective 1:

Quantitative Data Analysis

We will first conduct descriptive analyses. Our psychological and psychosocial measures are continuous or pseudo-continuous (e.g., sums of Likert-style questions) variables. Our outcomes

will be changes in psychosocial measures from baseline to follow-up. Descriptive analyses will include boxplots and summary measures by intervention arm (4 groups). Our formal analyses (those that test hypotheses) will take advantage of the factorial nature of this pilot cluster randomized control trial. These analyses will group together sites as receiving resilience intervention (yes vs. no) and receiving anti-stigma intervention (yes vs. no); therefore, results from two sites will be compared with results from two other sites. This gives us a larger sample size for each comparison and allows us to fit linear mixed effects models that include random effects to account for the correlation between measurements taken from participants at the same site while ensuring that the fixed effect of the intervention is identifiable. We will report results from models that are unadjusted and adjusted for a small number of HCW-level baseline covariates (age, sex, HCW role, and baseline measures of the outcome). Model diagnostics will be performed and outcome variables will be transformed, if necessary, to meet model assumptions.

Qualitative Interview Analysis:

Within two weeks of each interview, the research assistant and the PI will meet to discuss the findings. Audio files will be transcribed by a research assistant. The PI and a research analyst will code and analyze the interviews using MAXQDA 2022 software or similar. Thematic analysis will be used to identify responses to our questions about the drivers, core facilitators, and barriers to intervention acceptability and success.[81] Data will be coded by two independent coders to ensure that Cohen's Kappa is >85%. Three code maps will be developed to categorize data: (1) To understand the social, structural, and informational drivers, facilitators, and barriers to acceptability of resilience and anti-stigma training and (2) The potential of project sustainability, including interest, integration, and funding.

Objective 2:

With Objective 2 most of our outcomes are continuous measurements, and analyses will be similar to those described above: linear mixed effects models that take advantage of the factorial nature of outcome, with clusters defined as study sites, and unadjusted and adjusted for a small number of PLHIV-level covariates (age, sex, educational level, marital status, language, duration on ART, and history of ART medication pick-ups within the previous 6 months). For binary outcomes (e.g., undetectable viral load), we will fit generalized linear mixed effects models with a logit link function.

Every patient is given 30, 60, 90, or 180 days to pick up their ART medication, as indicated in the medical charts. If a patient picks up medication after the indicated/scheduled date, they will be considered "non-adherent" for each day after their specific pick-up date; this will be assessed over the course of the 6-month follow-up and will be treated as a continuous variable (a proportion between 0 and 1 for each participant). Participants who are lost to follow-up from the health facility during the 6-month follow-up period will be considered "non-adherent" for the days that they are lost. For persons who die or are known to have transferred care outside of the catchment area, the proportion of time on medication will be computed using only time prior to death or transfer of care. For our primary retention outcome (proportion of time on medication), normality assumptions are unlikely to hold, perhaps even after data transformation. Hence, we will fit a cumulative probability model (CPM) with fixed effects for the clinics. The CPM is well-suited for this setting because it does not require symmetry/normality in the outcome (which is bounded between 0 and 1 and likely not normal); in the absence of covariates, it reduces to the Wilcoxon rank sum test. The CPM has been shown to perform well in settings investigating medication adherence.[82,83] Specifically, the distribution of the proportion of time on medication will be modeled as

$\text{logit}(P(Y \leq y)) = \beta_0(y) + \beta_1 \text{Intervention} + \beta_s \text{site} + \beta_X X$, where β_1 is the effect of the intervention on the log-odds ratio scale. Our primary objective is to test the null hypothesis, H_0: $\beta_1 = 0$. We will provide estimates of β_1, 95% Wald confidence intervals, and two-sided p-values. As with our other analyses, we will take advantage of the factorial nature of the model by grouping interventions as receiving resilience intervention (yes vs. no) and receiving anti-stigma intervention (yes vs. no). An interaction between the two interventions will also be assessed to see, for example, if the interventions are synergistic. The primary model will be adjusted for study site to acknowledge similarities between patients at the same site, and it will also be adjusted for a small number of patient-level baseline covariates, that are usually predictive of adherence to medications (e.g., age, sex, and education). In the model with the interaction between two interventions, study site will not be included so that the interaction effects are identifiable. In additional crude secondary analyses, we will investigate how changes in HCW measures correlate with patient outcomes by including average HCW metrics in models, replacing study site with this continuous variable. These latter analyses will be very much exploratory, as with only four study sites, we will have limited information to estimate these associations.

We will also compute three secondary measures of patient retention:
(1) Monthly medication pick-up. Specifically, measured from the first day of ART initiation, any ART medication pick-up between days 16 and 45 will count as medication pick-up during month 1, any medication pick-up between days 46 and 75 will count as medication pick-up during month 2, and so forth, up until 6 months (i.e., medication pick-up between day 346 and 375); if the patient was enrolled on a three month pick up we will calculate on time pickups using the mark 15 days before and 15 days after the scheduled visit.
(2) Monthly medication pick-up using a "re-setting" of the ART medication pick-up timeframe for each subsequent month. Specifically, calculating next scheduled ART medication pick-up from the date of last (most recent) ART pick-up (*data to be obtained from "master card" documentation*), any ART medication pick-up between days 16 and 45 from next scheduled date will count as medication pick-up for that specific month. With each date of last (most recent) ART pick-up, the window for next scheduled medication pick-up will adjust accordingly;
(3a) For patients on monthly medication pick up. Retention at 6 months based on Mozambique Ministry of Health (MoH) guidelines. Specifically, at days 180 and 365 if the patient has had a documented ART pick-up within 59 days of their last scheduled pick-up date (*data to be obtained from pharmacy FILA form*), then they will be considered retained at that time point. If the patient has not had a documented ART pick-up in ≥60 days from their last scheduled pick-up date, they will be considered not retained (i.e., lost to follow-up);
(3b) For patients on a differentiated care model. Retention at 6 months will look at the most recent ART medication pick-up that occurred during the first 180 days and the date of the next scheduled pick-up falling within the 180 days or beyond; if that day falls before day 121 after initiating ART, the patient would not be considered retained at 6 months.

Objective 3

Within two weeks of each interview, the research assistant and the PI will meet to discuss the findings. Audio files will be transcribed by a research assistant. The PI and a research analyst will code and analyze the interviews using MAXQDA 2022 software or similar. Thematic analysis will be used to identify responses to our questions about the drivers, core facilitators, and barriers to intervention acceptability and success.[81] Data will be coded by two independent coders to ensure that Cohen's Kappa is >85%. One code map will be developed to categorize data: (1) to understand the factors related to the experience and occurrence of moral injury/ moral trauma

among HCW in the area, and (2) to understand what services or interventions may support HCW who are experiencing or at risk for moral injury/ moral trauma.

As the final surveys, anxiety and suicidality measures, will be assessed 10-11 months after the intervention, we are not expecting any impact of the intervention on these assessments. Because of this we will only conduct descriptive statistics, including summary measures across all four sites. We will compare the results of these measures by HCW gender, age, and site to look for trends in outcomes.

11. Ethical Considerations

The sites that participate in this proposal meet the requirements for the conduct of research using funds from the US Government. The protocol and consent forms will be reviewed and approved by the Vanderbilt University Medical Center IRB (FWA00005756, IRB00000475-7, IRB00002125) and the Institutional Committee of Health Bioethics-Zambézia, Mozambique (FWA00003139 IRB# IRB00002657). The proposed project is Non-Exempt Human Subjects Research.

All eligible health care staff will have the option to participate (or not) in the study without any implications on their job stability. The research activities will not alter in any way the treatment of HCW at the health facilities they work in, or the routine services that all patients are already expected to receive, nor will they adversely affect the rights and welfare of the study participants.

While we will obtain consent from all HCW who participate in the intervention and from those who complete any survey (HCW and PLHIV) or in-depth interview (HCW), we are requesting a waiver of consent for the population of adult PLHIV (who did not participate in a survey) whose clinical data will be extracted in a de-identified manner, due to:

- Data review will only involve a secondary analysis of routinely collected de-identified data and will not involve any interaction with human subjects.
- The data review involves no more than minimal risk to subjects.
- The research activities will not alter in any way the routine services that all patients are already expected to receive or adversely affect the rights and welfare of the subjects.
- Due to the high volume of patients and the inclusion of records for patients who might no longer be enrolled in care at these health facilities, the activity could not practicably be carried out without the waiver of consent.

Participant confidentiality

All participants who are consented in the study will be assigned a study ID number. Only study members will have the codebook that links the identifiers. Identifying information associated with these ID codes, such as names, will be kept in a data file separate from the survey data and clinic records. All data will be managed in a way that meets VUMC IRB and Mozambique Bioethics standards for the protection of human subjects and to ensure confidentiality and the protection of sensitive health information.

Consent Procedures

Review of study and participation information with potential subjects can be conducted in a group or individually but written informed consent must be obtained individually and in a confidential setting before any study procedure takes place (**Appendices 5-9**). Despite recruitment being done at the health facility, the study team will guarantee that interested individuals consent without any coercion, and that refusal of, interruption during, or withdrawal from the study will not result in negative consequences for receiving care (PLHIV patients) or for their professional work situation (Health Care Workers). A copy of the signed informed consent form will be offered to every participant. If an eligible individual is illiterate and/or unable to write or sign his/her name, he/she can provide a thumbprint in the presence of an independent literate witness. This witness must be present during the entire informed consent process and will sign the consent form as the witness only after the consenting participant has completed their thumbprint process. All written information, including the informed consent and other material to be used by participants and study staff will be translated from English into Portuguese and vice-versa, and will use vocabulary and language that are clearly understood. Although informed consent forms will be translated to Portuguese, verbal translation to main local languages (by study staff fluent in those languages) will be allowed to accommodate participants who do not speak Portuguese. Key phrases may be developed for main local languages to ensure correct verbal translation in the field by research assistants and to make the questions clearer to participants. Moreover, research assistants with fluency in Mozambique's major local languages will be hired to conduct surveys and interviews to increase inclusion of individuals who may not speak Portuguese fluently.

A participant may withdraw from the study at any time point. When a participant indicates to the study staff that they are withdrawing consent, this will be reported in the participant's source documents.

All participants will be informed that participation in the study is voluntary and refusal to participate will not affect their right to care and treatment at the health facility (PLHIV) or their employment and position at the health facility (HCW).

People living with HIV who are followed as part of routine care (n=~16,000) will not be formally recruited to participate in the study.

Evaluation of benefits and risks

Adverse events

Risks to the subjects: The level of risk associated with this research is expected to be minimal for all participants. Potential psychological discomfort may occur when administering the survey as many of the questions are personal and have to do with a stigmatized infectious disease and/or one's mental health and well-being, including suicidal ideation. Participants are able to decline to answer any question that they deem uncomfortable. If we identify a participant with suicidal ideation or severe depression, we will ensure they are referred to a psychologist for counseling to address their mental health concerns.

Participants (health care workers) who enroll in one of the two (or both) interventions will have the potential for inter-personal conflict as they brainstorm solutions to burnout or talk about stigmatizing experiences of patients.

Adverse Experience/Event (AE): We do not anticipate any adverse events as a result of this study, however, study participants will be provided with contact information (e.g., a telephone number) and instructed to contact study clinicians to report any serious AEs they experience.

Protection against risks: The study protocol and training manuals will include strict guidelines for conducting the survey and recording the data in a confidential manner. All study staff will receive formal responsible conduct of research training per NIMH, VUMC, C-Saúde, and Mozambican MOH guidelines. Participants may withdraw from the study or decline to participate in any study activity for any reason at any time, and they will be informed of this at the recruitment and enrollment stage prior to study participation.

Benefits
People living with HIV could benefit from this study if health care workers who receive the wellness and anti-stigma intervention provide more compassionate health services to PLHIV.

HCW in this study could potentially benefit from their additional resilience and anti-stigma training, which could help improve their own well-being.

12. Limitations

Our pilot cluster randomized controlled trial has the strength of being implemented in the most common type of health facility- a district clinic. We have designed our study in this way to be able to identify which intervention (or combination of interventions) is the most successful in both changing health care worker psychosocial characteristics and patient outcomes. Both outcomes will inform future iterations of this program. A cluster randomized controlled trial with only four sites is inherently limited, but we are using this data to inform the design of a fully powered future trial.

13. Dissemination Plan

Results from this study will be collected into a report and will be shared with MOH and the DPS-Z and other key stakeholders. The results will also be disseminated to government officials and health care workers working in these communities. If results are deemed by the authors to be potentially of interest to a wider scientific audience, we would plan on sharing these data in manuscript form, after obtaining appropriate clearances.

14. Budget

	unit cost	#	units		
HUMAN RESOURCES					
Research officer	MZN 50,000.00	1	7	MZN 350,000.00	$ 5,556
Research assistants (surveyors)	MZN 20,000.00	2	8	MZN 320,000.00	$ 5,079
TRAVEL & TRANSPORT					
MPT staff travel to Quelimane					

Travel to Quelimane from Maputo (2ps C-Saúde + 1 MOH); 2 trips	MZN 40,000.00	3	2	MZN 240,000.00	$ 3,810
Per diem Maputo teams on professional travels in MPT/QUEL	MZN 1,400.00	2	12	MZN 33,600.00	$ 533
Accommodation Maputo teams on professional travels in MPT/QUEL	MZN 5,000.00	2	12	MZN 120,000.00	$ 1,905
Per diem MOH staff to Zambezia	MZN 6,000.00	1	12	MZN 72,000.00	$ 1,143
Per diem DPS staff to sites for supervision	MZN 6,000.00	1	10	MZN 60,000.00	$ 952
Transport interviewers to sites	MZN 9,800.00	1	30	MZN 294,000.00	$ 4,667
TRAINING/PROJECT ACTIVITIES					
Training Sessions in Intervention Sites					
Food incentives for trainees	MZN 240.00	10	5	MZN 12,000.00	$ 190
Training Materials	MZN 15,000.00	1	1	MZN 15,000.00	$ 238
Incentives for MISAU Psychologists					$ -
Training stipend/per diem	MZN 850.00	1	5	MZN 4,250.00	$ 67
OTHER					
Tablets	MZN 21,000.00	1	4	MZN 84,000.00	$ 1,333
Bioethics Review Fees	MZN 20,000.00	1	1	MZN 20,000.00	$ 317
Transcription of interviews	MZN 3,000.00	1	30	MZN 90,000.00	$ 1,429
Translation of protocol/ interviews	MZN 20,000.00	1	1	MZN 20,000.00	$ 317
Surgical Masks	MZN 50.00	1	400	MZN 20,000.00	$ 317
Snack for sessions	MZN 240.00	400	3	MZN 288,000.00	$ 4,571
TOTAL COSTS				**MZN 2,042,850.00**	**$ 32,426**

15. Timeline

Time (month)	Activities/Description
Month 1	Recruit health care workers from four health facilities (n=100).

Month 1	Among HCW, assess baseline measures of (1) Resilience (2) Stigma (3) Burnout (4) Depersonalization (5) Moral Injury Questionnaire		
Months 1-4	Resilience/Wellness Intervention arm sessions; held bi-monthly	Resilience/Wellness and anti-stigma arm sessions, held bi-monthly	Anti-stigma arm intervention only sessions; held bi-monthly
Months 1-2 & Months 6-7	Recruit a sub-group of PLHIV patients receiving any HIV care and treatment into the study at the four study sites (total n=320) to assess impact of the interventions on medical mistrust, patient satisfaction, and perceived stigma from health care providers via baseline (study start) and end-line (approximately 6 months after study start) surveys.		
Months 1-12	Collect routine clinical data (retention, viral load) from all patients enrolled in care and treatment at the four study sites (n estimated approximately to be 16,000).		
Months 5-7	Among HCW, collect post-intervention surveys (repeat same measures as used at baseline, except for #5 Moral Injury Questionnaire) at all sites (control and intervention).		
Months 8-9	Recruit a sub-group of HCW participants at the three intervention sites for in-depth interviews related to moral injury/ moral trauma.		
Months 8-14	Conduct data analysis of survey outcomes among PLHIV and HCW.		
Months 10-11	Conduct surveys to assess depression, anxiety, and suicidality		
Months 12-15	Conduct data analysis of clinical outcomes among PLHIV.		
Months 12-18	Disseminate findings via community meetings with community members and clinicians		

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Appendix 1: Survey Questions (Objective 1: HCW surveys)

Sociodemographic data (*only to be collected at baseline survey*)

a. Age (years)
b. Sex
c. Marital status
d. Language knowledge – perception and speaking
e. Highest level of education
f. Category of role/position at the health facility
g. How long have you been working as a health care professional (years, months if <12 months)
h. How long have you been working in this health facility (years, months if <12 months)
i. Are you contracted by the National Health System (NHS) or a non-governmental organization (NGO)?

Measures for the HCW

Resilience

Response categories: Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree

1. I can enjoy my personal time without focusing on work matters.

2. I am able to disconnect from work communications during my free time (emails/phone, etc.).

3. I lose sleep over work issues.

4. I am able to free my mind from work when I am away from it.

5. I see every patients/client as an individual person with specific needs.

6. I care for all my patients equally even when it is difficult.

7. My work is meaningful.

8. The work I do makes a real difference.

HIV stigma (Provider Stigma)

Response categories: Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree

1. People living with HIV could have avoided HIV if they had wanted to

2. HIV is punishment for bad behavior

3. Most people living with HIV do not care if they infect other people

4. People living with HIV should feel ashamed of themselves

5. Most people living with HIV have had many sexual partners

6. People get infected with HIV because they engage in irresponsible behaviors

Anticipated Shame

7. I would be ashamed if I were infected with HIV

8. I would be ashamed if someone in my family were infected with HIV

Burnout

Response categories: i) “Always or to a very high degree”; ii) “Often or to a high degree”; iii) “Sometimes or somewhat seldom or to a low degree”; iv) “Never/almost never or to a very low degree"

Personal burnout

1. How often do you feel tired?
2. How often are you physically exhausted?
3. How often are you emotionally exhausted?
4. How often do you think: ’’I can’t take it anymore’’?
5. How often do you feel worn out?
6. How often do you feel weak and susceptible/vulnerable to illness?

Work-related burnout

1. Do you feel worn out at the end of the working day?
2. Are you exhausted in the morning at the thought of another day at work?
3. Do you feel that every working hour is tiring for you?
4. Do you have enough energy for family and friends during leisure time? (inverse scoring)
5. Do you find that your work is emotionally exhausting?
6. Does your work frustrate you?

7. Do you feel burnt out because of your work?

Client-related burnout

1. Do you find it hard to work with patients?
2. Does it drain your energy to work with patients?
3. Do you find it frustrating to work with patients?
4. Do you feel that you give more than you get back when you work with patients?
5. Are you tired of working with patients?
6. Do you sometimes wonder how long you will be able to continue working with patients?

Depersonalization

Response categories: “Never, A few times a year or less,” “Once a month or less,” “A few times a month,” “Once a week,” “A few times a week,” “Every day”

1. I have become more callous toward people since I took this job.

Moral Injury Questionnaire (only at baseline)

Moral Injury Symptom Scale: Healthcare Professionals Version (MISS-HF) The following questions may be difficult, but they are common experiences of busy healthcare professionals. They concern your experiences on your job as a health professional and how you are feeling now. Try to answer every question. Circle a single number between 1 (strongly disagree) and 10 (strongly agree) to indicate how much you personally agree or disagree with each statement.

1 = Strongly disagree
2 = Disagree
3 = Disagree somewhat
4 = Disagree a little bit
5 = Neutral (neither disagree nor agree)
6 = Agree a little bit
7 = Agree somewhat
8 = Agree
9 = Agree a lot
10 = Strongly agree

1. I feel betrayed by other health professionals whom I once trusted.
2. I feel guilt over failing to save someone from being seriously injured or dying.
3. I feel ashamed about what I've done or not done when providing care to my patients.
4. I am troubled by having acted in ways that violated my own morals or values.
5. Most people with whom I work as a health professional are trustworthy.
6. I have a good sense of what makes my life meaningful as a health professional.
7. I have forgiven myself for what's happened to me or to others whom I have cared for.
8. All in all, I am inclined to feel that I'm a failure in my work as a health professional.
9. I sometimes feel God is punishing me for what I've done or not done while caring for patients.
10. Compared to before I went through these experiences, my religious/spiritual faith has strengthened.
11. Do the feelings you indicated above cause you significant distress or impair your ability to function in relationships, at work, or other areas of life important to you? In other words, if you indicated any problems above, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Depression (only at endline) – response categories for 1-9 (not at all, several days, more than half the days, nearly every day)

Over the last two weeks, how often have you been bothered by any of the following problems:

1. In the last two weeks, how many days have you had little interest or pleasure in doing things?

2. In the last two weeks, how many days have you felt down, depressed, or hopeless

3. In the last two weeks, how many days have you had trouble falling or staying asleep, or sleeping too much.

4. In the last two weeks, how many days have you felt tired or having little energy.

5. In the last two weeks, how many days have you had poor appetite or overeating.

6. In the last two weeks, how many days have you felt like you do not like yourself, that you are a failure / not useful / have no worth or that you let yourself or your family down.

7. In the last two weeks, how many days have you had a lack of concentration in doing things, such as working, studying, home chores, or other activities.

8. In the last two weeks, how many days have you moved or spoken so slowing that other people have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual.

9. In the last two weeks, how many days have you thought that you would be better off dead, or of hurting yourself.

10. If you checked off any problems. How difficult have these problems made it for you to do your work, take care of things at home or get along with other people? (Not difficult at all, somewhat difficult, very difficult, extremely difficult)

Anxiety (only at endline) response categories for 1-7 (not at all, several days, more than half the days, nearly every day)

Over the last two weeks, how often have you been bothered by the following problems?

1. Feeling nervous, anxious, or on edge

2. Not being able to stop or control worrying

3. Worrying too much about different things.

4. Trouble relaxing

5. Being so restless that it is hard to sit still

6. Becoming easily annoyed or irritable

7. Feeling afraid, as if something awful might happen.

8. If you checked off any problems. How difficult have these problems made it for you to do your work, take care of things at home or get along with other people? (Not difficult at all, somewhat difficult, very difficult, extremely difficult)

Suicidality (Response categories yes/no)

1. In the last 30 days, have you thought it would be better or be dead or have you wished you were dead?

2. In the last 30 days have you thought of a way to commit suicide.

3. In the last 30 days, have you attempted suicide?

4. Have you ever made any suicide attempts throughout your life?

Appendix 2: Survey Questions (Objective 2: PLHIV surveys)

Sociodemographic data (*to be collected at each survey instance*)

a. Age (years)
b. Sex
c. Highest educational level
d. Marital status
e. What is your maternal language (language you grew up with)
f. Patient ID
g. Year in which you began HIV care at this health facility

Measures for People Living with HIV

Group-Based Medical Mistrust Scale (GBMMS) Items

Response categories: “Strongly agree”, “Agree”, “Disagree”, and “Strongly Disagree”

1. People living with HIV like me trust doctors and health care workers.

2. People living with HIV like me should be suspicious of modern or conventional medicine.

3. People living with HIV like me should be suspicious of information from doctors and health care workers.

4. People living with HIV like me receive the same medical care from doctors and health care workers as people from other groups.

5. Doctors have the best interests of people like me in mind.

6. Doctors and health care workers sometimes hide information from people like me.

7. I have personally been treated poorly or unfairly by doctors or health care workers because of who I am.

Patient Satisfaction

Response categories: “Strongly agree”, “Slightly agree”, “Neutral”, “Slightly disagree”, “Strongly disagree”

1. The provider takes care of me.

2. The provider explains the reasons for any requested medical tests.

3. The provider explains things in a way that is understandable.

4. I am confident of the health care providers' knowledge and skills.

5. Medical providers show respect for what I say.

6. The provider listens to me carefully.

7. The provider cares about me as a person.

8. The provider encourages me to talk about all my health concerns.

9. The provider spends enough time with me.

Perceived Provider Stigma (adapted from multiple sources)

Response categories: "Strongly agree", "Agree", "Disagree", and "Strongly Disagree"

1. Do healthcare workers touch you during your examination? (Yes/No)

    If no, why do you think they avoid touching you?

    a) Because I have HIV b) other reason (Please specify)

2. Telling a health care worker I have HIV is risky because they may disclose my status to others.

3. People with HIV are treated worse than patients without HIV by health care workers.

4. Most health care workers are uncomfortable around someone with HIV

5. Some health care workers do not care if someone with HIV lives or dies.

Appendix 3: Interview Guides for Health Care Workers Who Participated in the Interventions (Objective 1)

Demographic information

Age

Sex

Marital status

Education level

Academic training (*all levels achieved*)

Job position

Sector of work activity (in HF)

Community/province where born

Health care facility currently employed

Fluent in local language?

Family living with you in Zambézia (partner, children)?

Length of time you have been a health care worker?

Length of time you have been a health care worker at this health facility?

In addition to this HF, have you worked in particular in private clinics?

Are you a student in addition to working?

How many hours do you work per week (< 40 hours, 40 hours, > 40 hours a week)?

Do you have any close relatives living with HIV?

In-depth Interview Questions

1. Can you tell me about your experience attending the program? [specific which one depending on their site]

2. Think back to when you first hear about the program. Why did you decide to participate? What expectations did you have for the program when you first heard about it?

3. Now think about the program after you have participated. Did the program meet your expectations? If so, tell me ways that the program met your expectations.

a) What was good about the program? (What did you like about the program?)

4. Tell me ways the program did not meet your expectations? Are there any other expectations you had from the sessions that were not met?

a) In what ways did the program fail to succeed?

5. Can you tell me if the program changed the way your think or interact with colleagues or patients at work?

6. Can you tell me ways we could improve the program? [Probe: topic areas to cover, ways to deliver support, group vs individual setting]

7. Is there anything we could do to advocate for health care providers at the provincial or national level in order to improve their wellbeing?

a) What do you need to be successful (in general and at work)?

b) What do you need to improve your wellbeing?

Appendix 4: In-depth Interview Guide for Health Care Workers at Intervention Sites – Moral Injury Questions (Objective 3)

In-depth interview guide about moral injury/ moral trauma intervention and suicide

[*Interviewer will start the interview by summarizing moral injury study findings with the participant:]*

In our survey done with health care workers (HCW) in the area, we found that people had higher rates of something called "moral injury" than expected. Moral injury can occur when someone experiences, witnesses, or is involved in a situation(s) that conflicts with their own values or beliefs.

One example of an event that may lead to moral injury includes a patient who comes in for care that you know how to provide but you lack the medications or equipment to treat them – perhaps they suffer or die because you are unable to treat them, which goes against your own values/beliefs about patient care.

Another example is someone comes in at 22hrs with serious bleeding due to a pregnancy complication – and she is too ill to save with the treatment/materials that are on hand at the clinic. But instead of providing her support, you observe another HCW place the blame on the patient for "waiting to come in", and this other HCW's behavior goes against your own values for how to best support patients.

In our study, 36% of HCW participants showed signs of moderate moral injury. Moral injury can lead to higher levels of anxiety and depression, and potentially to suicidal ideation.

We want to chat with you about treating patients at your health facility and how the provision of care can negatively impact the health of HCW. We also want to talk with you about how we can help people working in the health system.

Interview questions:

1) After hearing what moral injury is (*remind them if necessary*), how important do you think this problem is in this health facility or in the province?
    a. probe: In your opinion, how common do you think this experience of moral injury might be among HCW in this area?
    b. probe: Have you ever experienced moral injury/ moral trauma? If so, please can you describe your experience?
    c. probe: How does it impact HCW's mental health (e.g., depression, anxiety, apathy, etc.)?
    d. probe: How does it affect the way they deliver care? (e.g., do they seem to have less empathy for patients? Do they have greater frustration with or depersonalization of patients?)

2) Do you know of any HCW who have become suicidal or had thoughts of suicide? If so, can you tell me about their experiences?

3) What are the biggest issues with working in the health field and in this health system in particular that could be causing high levels of moral injury? How have these issues impacted you?
    a. probes: Lack of medication, lack of materials, lack of human resources, work atmosphere, management issues, level of support from supervisors, others?
    b. probe: Are there any other minor issues related to working in the health field that could be causing moral injury? If so, can you describe how these impact you?

4) We understand that the health system is under capacitated, but we still want to support HCW. In your opinion, what could be done to reduce either the experience of or the impact of moral injury on HCW?

    a. Some changes have to be done at the health system level- like making sure there are enough drugs or hiring more people to help deliver care. What suggestions would you have to improve the health care system?
        i. Do you think this would be feasible to implement?

    b. Some services could be provided to individual HCW who are struggling- like offering counseling or support services to them specifically.
        i. How can we help HCW who feel lots of anxiety or depression?
        ii. How can we help HCW who feel like the health system is failing patients?
        iii. How can we help HCW who have thoughts of suicide or become suicidal?
            1. Do you think any of these would be acceptable to HCW? Would they be feasible to implement?

5) In our recent survey, we found low levels of burnout among HCW at several HF in the area. Burnout is characterized by a high degree of emotional exhaustion (e.g., fatigue, lack of motivation) and depersonalization (i.e., not caring for each patient as an individual, or cynicism) and a low sense of personal accomplishment at work. In many areas around the world, HCW have high levels of burnout, but here only 1% of participants showed moderate levels of burnout. Why do you think HCW in Zambézia show low levels of burnout?
    a. probe: Do you think that HCW in this area have ways of avoiding burnout/ staying resilient within their work? If yes, what are some of those the ways?

Appendix 5: Informed Consent Form (HCW in Intervention facilities, Objective 1)

Principal Investigator: Carolyn Audet *Revision Date*: 01 November 2023

Study Title: *Trabalhamos Juntos* (We Work Together): Improving HIV care delivery by capacitating health care providers
Institutions: Vanderbilt University Medical Center / Friends in Global Health

Informed Consent Form for Research (Health Care Worker, Intervention sites)

[**Research Assistant:** *This informed consent document applies to adults 18 years or older. A summary of all components of this document is to be read/verbalized aloud to the health care worker who participants in one of the study sites*.]

Age of participant: _____

Greetings, thank you for your interest. This form tells you about our research study. Please read/listen listen carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

This consent form contains information about a new study designed to test new interventions to improve the well-being of health care workers. You are being asked to participate in this study at a site with the intervention.

As a participant in the intervention group of this study, you will be asked to:

i. complete two surveys: (i) one now at study enrollment and (ii) within 1 month after the last session;
ii. participate in 4 to 8 intervention sessions that will last 1-2 hours each after work;
iii. some participants may be invited to also participate in an interview within 1 month after the last session.

Participation in the study is voluntary. If you agree to participate in this study, I will ask you to sign the form. Even if you agree to participate, you can stop participating at any time.

This form describes your rights as a participant of this study. It is meant to answer your questions. We will read this form to you. This form might contain some words that are unfamiliar to you. Please feel free to ask me any questions you may have about this or anything you do not understand.

Detailed Information:

Why are we doing this research and why are you asked to participate?

This study is being done by staff from Vanderbilt University Medical Center (VUMC), Friends in Global Health (FGH) and Ministry of Health (MOH). Our goal is to pilot two programs. One focuses on improving resilience among health care workers. The other focuses on strategies to overcome stigma and discrimination for patients living with HIV (PLHIV). These pilot interventions are being done in three health facilities, while in one other health facility, no pilot intervention is done and will be the comparison.

You are being asked to participate in this study because you are a practicing health care worker at a health facility site selected for the intervention group. If you agree to participate, you may receive one or both of the interventions.

Do you have to be in this research and can you stop if you want to?

Your participation is voluntary. This means that you can choose not to be in this research study if you do not want to participate. You can also stop being in this study at any time even if you enroll today. This is not a treatment study, so there are no alternative treatments. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

What will you do and how long will it take?

This study will last for the next 6 to 8 months. If you participate you will be asked to complete a survey at the beginning of the study. A study staff person will also conduct the same survey within 1 month after the last intervention session. If you give us permission, we can complete this survey at the health facility or at another nearby location of your choosing (depending on your preference). Each survey will take about 30 to 40 minutes to complete. You do not need to answer all the questions in the surveys if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the Interviewer that you do not want to answer the question. You can also stop the surveys at any time without any penalty.

In addition to the surveys, we will have between 4 and 8 program sessions at the health facility that we would like you to attend. You do not have to attend each session, but we hope you will find them valuable and chose to attend. Each session will last between 1-2 hours. We will try to make these sessions fun and enjoyable!

Lastly, based on your level of participation, your facility, and your job position, you may be selected to participate an in-depth interview after the completion of the sessions. This interview will be 30-45 minutes in length and will focus on understanding your perspectives about aspects of the program that were successful and those that need improvement.

We will ask to keep your contact number in case we want to schedule or reschedule the interview or the session. This number will be kept in a separate file, and will be destroyed when the study is finished.

What are the costs?

There will be no cost to you for participating in this study, other than your time. You will not receive any payment for participation.

What good things might come from this study?

a) The benefits to science and humankind that might result from this study: The information you share may help us to develop and tailor programs designed to help health care workers in Zambézia Province. This could benefit Mozambican society by improving their mental health and health care delivery for people living with HIV.
b) The benefits you might get from being in this study: There are no anticipated benefits for participants in this study, though participants may potentially enjoy the intervention sessions that will be offered.

Are there any risks or discomforts for this study? Can anything bad happen to you?

There are no expected risks for participants of this study. We do not anticipate that anything bad will happen to participants due to their involvement in this study. Still, we know that talking about your personal experiences with providing health care services here in Zambézia can be difficult. Some of the questions we ask might make you feel uncomfortable. We will try to have a comfortable, honest, and relaxed discussion. We will try to limit your discomfort and embarrassment as much as possible. If you feel any discomfort, please contact us as soon as possible so we can work to resolve it together. No study staff will tell anyone else your responses to the survey questions and we will ask all participants to keep discussions at our sessions private.

What are the unforeseeable risks?

In any research, there is the possibility of risks that cannot be planned for. In this study, there may be risks that we do not know about. We try to lower the risks by using trained staff to conduct the study survey, sessions, and interview. The staff will try to make you comfortable and to identify potential problems. We are also partnering with a health facility supported by the Ministry of Health (MOH) to make sure that everyone has access to the free healthcare services they need.

How can you find out the results of the study?

The results of this study will be shared with the health facility management and through a presentation at the locations where the study takes place. The results will also be written up into a final report and made available via publication of a manuscript.

What are the alternatives to participating?

This study is only looking at issues related to health care worker wellness and attitudes. We are not providing any medications or treatments as part of this study. If you choose not to participate in this study, you would not need to participate in the survey, intervention sessions, or interview.

What compensation will you receive for participating in the study?

You will not receive any monetary compensation for participating in the study. If you participate in any of the intervention sessions, you will receive a snack after the session as they will be organized in the afternoon after the main work hours.

Are there any reasons the researchers may remove you from the study?

If you enroll in the study, and the researchers later determine that you are ineligible for the study for any reason, they will inform you right away that you are not eligible or may not continue in the study and remove you from the study.

What happens if you choose to stop being in the study?

Nothing. You are free to stop participating at any point without problem. You only need to say that you would like to stop being in the study. You can tell this to us at any time.

Who can you talk to about this study?

If you have any questions about this study or wish to have additional counseling related to your involvement in this study, please feel free to contact the Study Coordinator, at the FGH office in Quelimane at Nº (+258) 24 21 71 00.

For more information about giving consent or your rights as a participant in this study, to discuss problems, concerns, questions, or to offer input, please feel free to contact:

- the Institutional Health Ethics Committee of Zambézia (CIBS-Z) at Nº (+258) 84 25 39 104 or Nº (+258) 82 57 55 437;
- the National Committee for Bioethics of Health in Mozambique (CNBS) at Nº (+258) 82 40 66 350; or
- the Vanderbilt University Medical Center (VUMC) Institutional Review Board (IRB) office in the U.S. at (+001) 615 322 2918 or toll free at (+001) 866 224 8273.

How will your confidentiality and privacy be maintained?

All efforts, within reason, will be made to keep your personal information in your research record confidential. However, it is not possible to guarantee total confidentiality. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name.

Your information collected during these surveys will be kept in locked filing cabinets or on password-protected computers and hard drive servers at the FGH office in Quelimane and at VUMC in the U.S. Only study researchers trained in data management and confidentiality will have access to your information.

Your information may only be shared if you or someone else is in danger, or if we are required to do so by law. If this occurs, your information may be shared with VUMC, or the U.S. and/or Mozambican government. This includes, for example, the VUMC IRB, U.S. Federal Government Office for Human Research Protections, or the Mozambican Ministry of Health.

Do you have any questions?

This form has been read and explained to you. You have been given an opportunity to ask questions about the study. You know that you may decide at any time to not continue participating in the study. You understand that you will receive a copy of this consent form. By saying yes, you agree to participate in two surveys: one now and a second one within one month of the last session. You are agreeing to participate in the program sessions and an interview if you would be selected for the interview. If you say no, you decline to participate in all parts of the study.

Moderator: Answer the participant's questions before proceeding to the next question.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Do you agree to participate in the study? [**Research Assistant**: *mark the participant's response here*]

[ ] No [**Research Assistant:** *thank the individual for their time*]

[ ] Yes [**Research Assistant:** *ensure that the participant documents their name below*]

Do you agree to give your contact number to be used ONLY in the study? [**Research Assistant**: *mark the participant's response here*]

[ ] No

[ ] Yes

Do you agree to participate in the in-depth interview, if selected for one? [**Research Assistant**: *mark the participant's response here*]

[ ] No

[ ] Yes

Do you agree to record the interview if agreeing with the in-depth interview? [**Research Assistant**: *mark the participant's response here*]

[ ] No

[ ] Yes

_____ _____

Printed Name of Participant Date

_____ _____

Signature of Participant Date

STATEMENT BY RESEARCH ASSISTANT

I have explained to the participant the study purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability.

_____ _____

Signature of Research Assistant Date

Appendix 6: Informed Consent Form (HCW, Control Group, Objective 1)

Principal Investigator: Carolyn Audet *Revision Date*: 01 November 2023

Study Title: *Trabalhamos Juntos* (We Work Together): Improving HIV care delivery by capacitating health care providers
Institutions: Vanderbilt University Medical Center / Friends in Global Health

Informed Consent Form for Research (Health Care Worker, Control sites)

[**Research Assistant:** *This informed consent document applies to adults 18 years or older. A summary of all components of this document is to be read aloud/verbalized to the participants***.**]

Age of participant: _____

Greetings, thank you for your interest. This form tells you about our research study. Please read/listen carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

This consent form contains information about a new study designed to test new interventions to improve the well-being of health care workers. You are being asked to participate in this study at a site without the intervention, also called a control site.

As a participant in the control group of this study, you will be asked to complete two surveys: (i) one now at study enrollment, and (ii) again approximately 6 months after study start.

Participation in the study is voluntary. If you agree to participate in this study, I will ask you to sign the form. Even if you agree to participate, you can stop participating at any time.

This form describes your rights as a participant of this study. It is meant to answer your questions. We will read this form to you. This form might contain some words that are unfamiliar to you. Please feel free to ask me any questions you may have about this or anything you do not understand.

Detailed Information:

Why are we doing this research and why are you asked to participate?

This study is being done by staff from Vanderbilt University Medical Center (VUMC), Friends in Global Health (FGH), and Ministry of Health (MOH). Our goal is to pilot two programs. One focuses on improving resilience among health care workers. The other focuses on strategies to overcome stigma and discrimination for patients living with HIV (PLHIV). These pilot interventions are done in three health facilities, while in one health facility, no pilot intervention is done and this will be the comparison (or "control") site.

You are being asked to participate in this study because you are a practicing health care worker at a health facility selected to be a control site. If you agree to participate in this study, you will not receive either of the interventions. Instead, we will compare outcomes at this site with those from the three intervention sites.

Do you have to be in this research and can you stop if you want to?

Your participation is voluntary. This means that you can choose not to be in this research study if you do not want to participate. You can also stop being in this study at any time even if you enroll today. This is not a treatment study, so there are no alternative treatments. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

What will you do and how long will it take?

This study will last for the next 6 to 8 months. If you participate you will be asked to complete a survey at the beginning of the study. A study staff person will also conduct the same survey again approximately five to six months after study start. Each survey will take about 30 to 40 minutes to complete. If you give us permission, we can complete this survey at the health facility or at another nearby location of your choosing (depending on your preference). You do not need to answer all the questions in the surveys if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the Interviewer that you do not want to answer the question. You can also stop the surveys at any time without any penalty.

We will ask to keep your contact number in case we want to schedule or reschedule the survey. This number will be kept in a separate file, and will be destroyed when the study is finished.

What are the costs?

There will be no cost to you for participating in this study, other than your time. You will not receive any payment for participation.

What good things might come from this study?

a) The benefits to science and humankind that might result from this study: The information you share may help us to develop and tailor programs designed to help health care workers in Zambézia Province. This could benefit Mozambican society by improving their mental health and health care delivery for people living with HIV.
b) The benefits you might get from being in this study: There are no anticipated benefits for participants in this study, though participants may potentially enjoy discussing the topics in the survey.

Are there any risks or discomforts for this study? Can anything bad happen to you?

There are no expected risks for participants of this study. We do not anticipate any possible risks or harms with participating in these two surveys. Still, we know that talking about your personal experiences with providing health care services here in Zambézia can be difficult. Some of the questions we ask might make you feel uncomfortable. We will try to have a comfortable, honest, and relaxed environment to complete each survey. We will try to limit any discomfort as much as possible. If you feel any discomfort, please contact us as soon as possible so we can work to resolve it together. No study staff will tell anyone else your responses to the survey questions.

What are the unforeseeable risks?

In any research, there is the possibility of risks that cannot be planned for. In this study, there may be risks that we do not know about. We try to lower the risks by using trained staff to conduct this survey. The staff will try to make you comfortable and to identify potential problems. We are also partnering with a health facility supported by the Ministry of Health (MOH) to make sure that everyone has access to the free healthcare services they need.

How can you find out the results of the study?

The deidentified results of this study will be shared with the Ministry of Health and via meetings at health facilities where the study takes place. The results will also be written up into a final report and made available via publication of a manuscript.

What are the alternatives to participating?

This study is only looking at issues related to health care worker wellness and attitudes. We are not providing any medications or treatments as part of this study. If you choose not to participate in this study, you would not need to participate in the survey.

What compensation will you receive for participating in the study?

You will not receive any monetary compensation for participating in the study.

Are there any reasons the researchers may remove you from the study?

If you enroll in the study, and the researchers later determine that you are ineligible for the study for any reason, they will inform you right away that you are not eligible or may not continue in the study and remove you from the study.

What happens if you choose to stop being in the study?

Nothing. You are free to stop participating at any point without problem. You only need to say that you would like to stop. You can tell this to us at any time.

Who can you talk to about this study?

If you have any questions about this study or wish to have additional counseling related to your involvement in this study, please feel free to contact the Study Coordinator, at the FGH office in Quelimane at Nº (+258) 24 21 71 00.

For more information about giving consent or your rights as a participant in this study, to discuss problems, concerns, questions, or to offer input, please feel free to contact:

- the Institutional Health Ethics Committee of Zambézia (CIBS-Z) at Nº (+258) 84 25 39 104 or Nº (+258) 82 57 55 437;
- the National Committee for Bioethics of Health in Mozambique (CNBS) at Nº (+258) 82 40 66 350; or
- the Vanderbilt University Medical Center (VUMC) Institutional Review Board (IRB) office in the U.S. at (+001) 615 322 2918 or toll free at (+001) 866 224 8273.

How will your confidentiality and privacy be maintained?

All efforts, within reason, will be made to keep your personal information and your responses to this survey confidential. However, it is not possible to guarantee total confidentiality. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name.

Your information collected during these surveys will be kept in locked filing cabinets or on password-protected computers and hard drive servers at the FGH office in Quelimane and at VUMC in the U.S. Only study researchers trained in data management and confidentiality will have access to your information.

Your information may only be shared if you or someone else is in danger, or if we are required to do so by law. If this occurs, your information may be shared with VUMC, or the U.S. and/or Mozambican government. This includes, for example, the VUMC Institutional Review Board (IRB), U.S. Federal Government Office for Human Research Protections, or the Mozambican Ministry of Health.

Do you have any questions?

This form has been read and explained to me. I have been given an opportunity to ask questions I have about the surveys. I understand that I may decide at any time that I do not want to continue participating in the two surveys. I understand that I can receive a copy of this consent form. By saying yes, you agree to participate in this health care worker survey. By saying no, you decline to participate in the surveys.

Moderator: Answer the participant's questions before proceeding to the next question.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Do you agree to participate in the study? [**Research Assistant**: *mark the participant's response here*]

[ ] No [**Research Assistant:** *thank the individual for their time*]

[ ] Yes [**Research Assistant:** *ensure that the participant documents their name below*]

Do you agree to give your contact number to be used ONLY in the study? [**Research Assistant**: *mark the participant's response here*]

[ ] No

[ ] Yes

_____ _____

Printed Name of Participant Date

_____ _____

Signature of Participant Date

STATEMENT BY RESEARCH ASSISTANT

I have explained to the participant the purpose of the interview and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability.

_____ _____

Signature of Research Assistant Date

Appendix 7: Informed Consent Form (PLHIV Participants, Objective 2)

Principal Investigator: Carolyn Audet *Revision Date*: 01 November 2023

Study Title: *Trabalhamos Juntos* (We Work Together): Improving HIV care delivery by capacitating health care providers
Institutions: Vanderbilt University Medical Center / Friends in Global Health

Informed Consent Form for Research (Patient Participants)

[**Research Assistant:** *This informed consent document applies to adults 18 years or older. A summary of all the components of this document is to be read aloud/verbalized to the participants*.]

Age of participant: _____

Greetings, thank you for your interest. This form tells you about our research study. Please read/listen carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

This consent form contains information about a new study designed to test new interventions to improve the well-being of health care workers. You are being asked to participate in this study because you receive care provided by these health care workers at a site where the intervention is being piloted.

As a participant of this study, you will be asked to complete a survey which we will conduct today. If you agree, we will also collect information on your medication pick-up data from the last year from your medical file.

Participation in the study is voluntary. If you agree to participate in this study, I will ask you to sign the form or make your thumbprint mark. Even if you agree to participate, you can stop participating at any time.

This form describes your rights as a participant of this study. It is meant to answer your questions. We will read this form to you. This form might contain some words that are unfamiliar to you. Please feel free to ask me any questions you may have about this or anything you do not understand.

Detailed Information:

Why are we doing this research and why are you asked to participate?

This study is being done by staff from Vanderbilt University Medical Center (VUMC), Friends in Global Health (FGH), and Ministry of Health (MOH). Our goal is to try out two new programs. One will work on improving resistance to stress among health care workers. The other will help health care workers to overcome stigma and discrimination for patients. These pilot interventions are being done in three health facilities, while in one health facility, no pilot intervention is done and this site will be the comparison (or "control") site.

You are being asked to participate in this study because you receive care provided by these health care workers. As a patient at this health facility you will not directly participate in any activity of the intervention. But we hope that the intervention will help the communication and support between healthcare worker and patient.

Do you have to be in this research and can you stop if you want to?

Your participation is voluntary. This means that you can choose not to be in this research study if you do not want to participate. You can also stop being in this study at any time even if you enroll today. You do not need to answer all the questions in the survey if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the Interviewer that you do not want to answer the question.

This is not a treatment study, so there are no alternative treatments. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

What will you do and how long will it take?

The survey is done at the beginning of the study and 5 to 6 months later.

[***Research Assistant****: if at start of study*] We are now at the start of the study. There is no problem if you would do the survey two times (now and at the end). If you would be invited for a second survey, we will explain the study again and ask again for your permission to participate.

[***Research Assistant****: if at end of study*] We are now at the end of the study. There is no problem if you have also done a survey at the start of the study.

If you agree to participate today, you will be asked to complete a survey. The survey will take about 30-40 minutes to complete. If you give us permission, we can complete this survey at the health facility or at a nearby location of your choosing (depending on your preference). You do not need to answer all the questions in the survey if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the Interviewer that you do not want to answer the question. You can also stop the survey at any time without any penalty.

If you agree to participate in this study, we will also access your medical record to record the dates you have picked up your medications in the past 12 months.

Aside from participating in the survey, there is nothing you need to do for us to collect that information.

What are the costs?

There will be no cost to you for participating in this survey, other than your time. You will not receive any payment for participation.

What good things might come from this study?

a) The benefits that might result from this study: The information you share may help us to develop and tailor programs designed to help health care workers in Zambézia Province. This could benefit Mozambican society by improving their mental health and health care delivery for people living with HIV.
b) The benefits you might get from being in this study: There are no anticipated benefits for participants in this study, though participants may potentially enjoy answering the questions in the survey.

Are there any risks or discomforts for this study? Can anything bad happen to you?

There are no expected risks for participants of this study. We do not anticipate any possible risks with participating in the survey. Still, we know that talking about your personal experiences with receiving health care services here in Zambézia may be difficult. Some of the questions we ask might make you feel uncomfortable. We will try to have a comfortable, honest, and relaxed environment to complete the survey. We will try to limit any discomfort as much as possible. If you feel any discomfort, please contact us as soon as possible so we can work to resolve it together. No study staff will tell anyone else your responses to the survey questions.

What are the unforeseeable risks?

In any research, there is the possibility of risks that cannot be planned for. In this study, there may be risks that we do not know about. We try to lower the risks by using trained staff to conduct this survey. The staff will try to make you comfortable and to identify potential problems.

How can you find out the results of the study?

The results of this study will be shared with the Ministry of Health and to health facilities where the study took place through a community meeting. The results will also be written up into a final report and made available via publication of a manuscript.

What are the alternatives to participating?

This study is only looking at issues related to health care worker wellness and attitudes. We are not providing any medications or treatments as part of this study. If you choose not to participate in this study, you would not need to participate in the survey. Nothing about your care and treatment at this health facility will other change or be affected if you do or do not participate.

What compensation will you receive for participating in the study?

You will not receive any monetary compensation for participating in the study.

Are there any reasons the researchers may remove you from the study?

If you enroll in the study, and the researchers later determine that you are ineligible for the study for any reason, they will inform you right away that you are not eligible or may not continue in the study and remove you from the study.

What happens if you choose to stop being in the study?

Nothing. You are free to stop participating at any point without problem. You only need to say that you would like to stop. You can tell this to us at any time.

Who can you talk to about this study?

If you have any questions about this study or wish to have additional counseling related to your involvement in this study, please feel free to contact the Study Coordinator, at the FGH office in Quelimane at Nº (+258) 24 21 71 00.

For more information about giving authorization or your rights as a participant in this study, to discuss problems, concerns, questions, or to offer input, please feel free to contact:

- the Institutional Health Ethics Committee of Zambézia (CIBS-Z) at Nº (+258) 84 25 39 104 or Nº (+258) 82 57 55 437;
- the National Committee for Bioethics of Health in Mozambique (CNBS) at Nº (+258) 82 40 66 350; or
- the Vanderbilt University Medical Center (VUMC) Institutional Review Board (IRB) office in the U.S. at (+001) 615 322 2918 or toll free at (+001) 866 224 8273.

How will your confidentiality and privacy be maintained?

All efforts, within reason, will be made to keep your personal information and your responses to this survey private. However, it is not possible to guarantee total privacy. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name.

Your information collected during this study will be kept in locked filing cabinets or on password-protected computers and hard drive servers at FGH and VUMC. Only study researchers trained in data management and confidentiality will have access to your information.

Your information may only be shared if you or someone else is in danger, or if we are required to do so by law. If this occurs, your information may be shared with VUMC, or the U.S. and/or Mozambican government. This includes, for example, the VUMC Institutional Review Board (IRB), U.S. Federal Government Office for Human Research Protections, or the Mozambican Ministry of Health.

Do you have any questions?

This form has been read and explained to me. I have been given an opportunity to ask questions I have about the survey. I understand that I may decide at any time that I do not want to continue participating in the survey. I understand that I can receive a copy of this consent form. By saying yes, you agree to participate in the participant survey. You then also agrees to give access to the data of your treatment from your medical file. By saying no, you decline to participate in the survey and/ or giving access to your medical data.

Moderator: Answer the participant's questions before proceeding to the next question.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read/ been read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Do you agree to participate in the study (survey and use of information regarding your treatment from the medical record)? [**Research Assistant**: *mark the participant's response here*]

[ ] No [**Research Assistant:** *thank the individual for their time*]

[ ] Yes [**Research Assistant:** *ensure that the participant or witness document the participant's name below*]

_____ _____

Printed Name of Participant Date

_____ _____

Signature of Participant Date

_____ _____

Printed Name of Witness Date **AND**

_____ _____

Signature of Witness (if thumbprint used) Date

Thumbprint of Participant

STATEMENT BY RESEARCH ASSISTANT

I have explained to the participant the purpose of the survey and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability.

_____ _____

Signature of Research Assistant Date

Appendix 8: Informed Consent Form (In-depth interview regarding moral injury with HCW participants at intervention sites, Objective 3)

Principal Investigator: Carolyn Audet *Revision Date*: 06 August 2024
Study Title: *Trabalhamos Juntos* (We Work Together): Improving HIV care delivery by capacitating health care providers
Institutions: Vanderbilt University Medical Center / Friends in Global Health / C-Saúde

Informed Consent Form for Research (Health Care Worker, Intervention sites)

[**Research Assistant:** *This informed consent document applies to adults 18 years or older. A summary of all components of this document is to be read/verbalized aloud to the health care worker who participants in one of the study sites*.]

Age of participant: _____

Greetings, thank you for your interest. This form tells you about our research study. Please read/listen carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

This consent form contains information about a new study designed to test new interventions to improve the well-being of health care workers.

As a participant in the intervention group of this study, you will be asked to participate in an interview to talk about the treatment of patients in this health facility and how the provision of care can potentially negatively impact the wellbeing or health of health care workers. We also want to talk to you about how we can help people who work in the health system.

Participation in the interview is voluntary. If you agree to participate in this interview, I will ask you to sign the form. Even if you agree to participate, you can stop participating at any time.

This form describes your rights as a participant of this interview. It is meant to answer your questions. We will read this form to you. This form might contain some words that are unfamiliar to you. Please feel free to ask me any questions you may have about this or anything you do not understand.

Detailed Information:

Why are we doing this research and why are you asked to participate?

This study is being done by staff from Vanderbilt University Medical Center (VUMC), Friends in Global Health (FGH)/ Centro pela Saúde Global (C-Saúde) and Ministry of Health (MOH). In the activities we have carried out in this study, our goal was to pilot two programs. One focused on improving resilience among health care workers. The other focused on strategies to overcome stigma and discrimination for patients living with HIV (PLHIV). These pilot interventions were done in three health facilities, while in one other health facility, no pilot intervention was done and served as the comparison.

In our survey with health care workers in the beginning of the study, we found that health care workers had higher rates of something called moral injury than expected. Moral injury can occur when someone engages in, fails to prevent, or witnesses acts that conflict with their values or beliefs. One example of an event that may lead to moral injury include a patient who comes in for care that you know how to provide but you lack the medications or equipment to treat them – perhaps they suffer or die because you cannot treat them.

You are being asked to participate in this interview because you are a practicing health care worker at a health facility site selected for the intervention group.

Do you have to be in this research and can you stop if you want to?

Your participation is voluntary. This means that you can choose not to be in this interview if you do not want to participate. You can also stop being in the interview at any time. This is not a treatment study, so there are no alternative treatments. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

What will you do and how long will it take?

If you agree to take part, you will participate in an interview where we will talk about providing care to patients in this health facility and how providing care could potentially negatively impact the health of health care workers. We also want to talk to you about how we can help the people who work in the system. This interview will be 30-45 minutes in length.

You do not need to answer all the questions in the interview if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the Interviewer that you do not want to answer the question. You can also stop the interview at any time without any penalty.

What are the costs?

There will be no cost to you for participating in this interview, other than your time. You will not receive any payment for participation.

What good things might come from this study?

a) The benefits to science and humankind that might result from this interview: The information you share may help us to develop and tailor programs designed to help health care workers in Zambézia Province. This could benefit Mozambican society by improving their mental health and health care delivery for people living with HIV.
b) The benefits you might get from being in this interview: There are no anticipated benefits for participants in this study, though participants may potentially enjoy participating in the interview.

Are there any risks or discomforts for this study? Can anything bad happen to you?

There are no expected risks for participants of this interview. We do not anticipate that anything bad will happen to participants due to their involvement in this interview. Still, we know that talking about your personal experiences with providing health care services here in Zambézia can be difficult. Some of the questions we ask might make you feel uncomfortable. We will try to have a comfortable, honest, and relaxed discussion. We will try to limit your discomfort and embarrassment as much as possible. If you feel any discomfort, please contact us as soon as possible so we can work to resolve it together. No study staff will tell anyone else your responses to the interview questions.

What are the unforeseeable risks?

In any research, there is the possibility of risks that cannot be planned for. In this study, there may be risks that we do not know about. We try to lower the risks by using trained staff to conduct the interview. The staff will try to make you comfortable and to identify potential problems. We are also partnering with a health facility supported by the Ministry of Health (MOH) to make sure that everyone has access to the free healthcare services they need.

How can you find out the results of the study?

The results of this study will be shared with the health facility management and through a presentation at the locations where the study takes place. The results will also be written up into a final report and made available via publication of a manuscript.

What are the alternatives to participating?

This study is only looking at issues related to health care worker wellness and attitudes. We are not providing any medications or treatments as part of this interview. If you choose not to participate in this study, you would not need to participate in the interview.

What compensation will you receive for participating in the study?

You will not receive any monetary compensation for participating in the interview.

Are there any reasons the researchers may remove you from the study?

If you enroll in the interview, and the researchers later determine that you are ineligible for the interview for any reason, they will inform you right away that you are not eligible or may not continue in the interview and your data will be removed.

What happens if you choose to stop being in the study?

Nothing. You are free to stop participating at any point without problem. You only need to say that you would like to stop being in the interview. You can tell this to us at any time.

Who can you talk to about this study?

If you have any questions about this study or wish to have additional counseling related to your involvement in this study, please feel free to contact the Study Coordinator, at the FGH/ C-Saúde office in Quelimane at Nº (+258) 24 21 71 00.

For more information about giving consent or your rights as a participant in this study, to discuss problems, concerns, questions, or to offer input, please feel free to contact:

- the Institutional Health Ethics Committee of Zambézia (CIBS-Z) at Nº (+258) 84 25 39 104 or Nº (+258) 82 57 55 437;
- the National Committee for Bioethics of Health in Mozambique (CNBS) at Nº (+258) 82 40 66 350; or
- the Vanderbilt University Medical Center (VUMC) Institutional Review Board (IRB) office in the U.S. at (+001) 615 322 2918 or toll free at (+001) 866 224 8273.

How will your confidentiality and privacy be maintained?

All efforts, within reason, will be made to keep your personal information in your research record confidential. However, it is not possible to guarantee total confidentiality. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name.

Your information collected during this interview will be kept in locked filing cabinets or on password-protected computers and hard drive servers at the FGH/ C-Saúde office in Quelimane and at VUMC in the U.S. Only study researchers trained in data management and confidentiality will have access to your information.

Your information may only be shared if you or someone else is in danger, or if we are required to do so by law. If this occurs, your information may be shared with VUMC, or the U.S. and/or Mozambican government. This includes, for example, the VUMC IRB, U.S. Federal Government Office for Human Research Protections, or the Mozambican Ministry of Health.

Do you have any questions?

This form has been read and explained to you. You have been given an opportunity to ask questions about the study. You know that you may decide at any time to not continue participating in the study. You understand that you will receive a copy of this consent form. By saying yes, you agree to participate in the interview. If you say no, you decline to participate in the interview.

Moderator: Answer the participant's questions before proceeding to the next question.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Do you agree to participate in the in-depth interview, if selected for one? [**Research Assistant**: *mark the participant's response here*]

[ ] No

[ ] Yes

Do you agree to record the interview if agreeing with the in-depth interview? [**Research Assistant**: *mark the participant's response here*]

[ ] No

[ ] Yes

_____ _____

Printed Name of Participant Date

_____ _____

Signature of Participant Date

STATEMENT BY RESEARCH ASSISTANT

I have explained to the participant the study purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability.

_____ _____

Signature of Research Assistant Date

Appendix 9: Routinely collected clinical data of all PLHIV to be extracted from EPTS (Objective 2)

1. Age
2. Sex
3. Date of HIV diagnosis
4. Education level (highest completed)
5. Marital status
6. Number of children alive
7. HIV status disclosed to family (yes/no)
8. ART initiation date
9. ART pick up dates (all during study period)
10. Scheduled ART pick up dates (all during study period)
11. Clinical appointment dates (all during study period)
12. Scheduled clinical appointment dates (all during study period)
13. Viral Load test results and dates (all during study period)
14. Pregnancy status at time of study.
15. Differentiated model of care (all documented during study period)
16. Type of drug dispensation (all documented during study period)
17. Blood pressure (all results during study period)
18. Weight (all results during study period)
19. Height
20. TB treatment
21. WHO staging
22. patient ID
23. CD4 results and dates (all during study period)

Appendix 10: Clinical data to be extracted from EPTS for only the PLHIV participating in the survey (Objective 2)

1. Patient ID
2. Date of enrollment in HIV services
3. ART initiation date
4. ART pick up dates (all in previous 6 months)
5. Scheduled ART pick up dates (all in previous 6 months)
6. Differentiated model of care (all in previous 6 months)
7. Viral Load test results and dates (all in previous 6 months)
8. Type of drug dispensation (all documented in previous 6 months)